Proposed Proprietary Laboratory Analyses Panel Meeting Agenda - November 2022 Meeting

The proposed agenda for the November 2022 CPT® Proprietary Laboratory Analyses Panel meeting identifies the test names and requested descriptions for each test. The laboratory test name and test description detailed in this document are extracted from Applications submitted for discussion at this meeting. **Until such time as the Technical Advisory Group acts on these requests, the information that appears in this Proposed Agenda is provided for informational purposes only.**

NOTICE –INTERESTED PARTY PROCESS

Upon review of this agenda, if the reviewer believes that they will need to provide comment on an issue, they must seek Interested Party status by submitting a request for a copy of the application and associated materials. **Only requests submitted through Zendesk will be approved.** This request for review of the agenda materials should contain the identity of the interested party seeking such and a brief summary of the basis for the request (e.g., associated vendor/ industry representative).

Any interested parties wishing to provide written comments on any agenda items should be aware of the relevant deadlines for reviewing and providing written comments to allow review by all parties (eg, Panel members, Technical Advisory Group reviewers, applicants, etc.). The applicant(s) who submitted the original code change application is automatically considered an interested party and is notified by AMA staff of any request for review submitted by another party. Interested parties should be advised of the expedited deadlines of the PLA code development process to facilitate quarterly submission, review and publication of Proprietary Laboratory Analyses Applications, in accordance with the timeframes defined in the Proprietary Laboratory Analyses (PLA) Calendar.

*Interested party requests will not be processed until the interested party submits a signed confidentiality agreement and disclosure of interest form. Interested party requests will be processed within 5 days of receipt of the requested forms. Written comments for these requests are due within 3 days upon receipt of materials, unless extenuating circumstances preclude the ability for interested parties to provide written comments for consideration within the defined timeframes.

During the time between now and the date of the meeting, the agenda will, most likely, be modified to reflect changes – additions, deletions or updates.

ID	Laboratory Test Name	Proposed Test Description
100919	clonoSEQ® Assay	Oncology (lymphoid-cancer), genomic sequence analysis (DNA), using multiplex PCR and next-generation sequencing, with algorithm for identification and quantification of dominant clonal sequence(s), to assess minimal residual disease (MRD) and changes in disease burden, reported as absence or presence of MRD with quantitation of disease burden
101152	3D Predict™ Ovarian Doublet Panel - **Delete 0324U**	~~**0324U** Oncology (ovarian), spheroid cell culture, 4-drug panel (carboplatin, doxorubicin, gemcitabine, paclitaxel), tumor chemotherapy response prediction for each drug~~
101153	3D Predict™ Ovarian PARP Panel - **Delete 0325U**	~~**0325U** Oncology (ovarian), spheroid cell culture, poly (ADP-ribose) polymerase (PARP) inhibitors (niraparib, olaparib, rucaparib, velparib), tumor response prediction for each drug~~
101161	Oncuria Detect	Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) using immunoassays, utilizing voided urine sample with diagnostic algorithm which includes patient's age, race and gender reported as a probability of harboring cancer.
101162	Oncuria Monitor	Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) using immunoassays, utilizing voided urine sample with diagnostic algorithm which includes patient's age, race and gender reported as a probability of a recurring cancer.
101163	Oncuria Predict	Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) using immunoassays, utilizing voided urine sample with diagnostic algorithm reported as a risk score
101164	Urogenital pathogen with Rx panel (UPX)	Infectious agent detection by nucleic acid DNA/RNA. genitourinary pathogens. identification of 21 bacterial and fungal organisms and identification of 21 associated antibiotic resistance genes, multiplex amplified probe technique.
101180	OVAWatch℠	Oncology (ovarian cancer), 7 assays (Follicle stimulating Hormone, Human Epididymis Protein 4, Apolipoprotein A-1, Transferrin, Transthyretin, beta-2 macroglobulin, Prealbumin, and Cancer Antigen 125) used to generate the OvaWatch Risk score, demographic data, utilizing serum, algorithm reported as scores of ovarian cancer risk
101182	Esophageal String Test (EST) – **Revise 0095U**	**▲0095U** ~~Inflammation (~~E~~e~~osinophilic esophagitis~~), ELISA analysis of~~, 2 protein biomarkers (Eeotaxin-3 ~~{~~[CCL26 ~~[~~{C-C motif chemokine ligand 26~~]}~~}] ~~and~~ major basic protein ~~{~~[PRG2 ~~[~~{proteoglycan 2, pro eosinophil major basic protein~~]},~~}]), enzyme-linked immunosorbent assays (ELISA) specimen obtained by ~~swallowed nylon~~ esophageal string test device, algorithm reported as p~~redictive pr~~obability ~~index for~~ of active or inactive ~~e~~Eosinophilic

		esophagitis. Proprietary Name/manufacturer: Esophageal String Test (EST), EnteroTrack, LLC.
101184	ArteraAI Prostate Test	Oncology (prostate), image analysis with artificial intelligence assessment of at least 128 image features of formalin fixed paraffin embedded cancer tissue plus clinical factors, reported as prognostic algorithm regarding distant metastasis and prostate cancer specific mortality and, when applicable, predictive algorithm regarding response to androgen deprivation therapy.
101185	Liposcale®	Dyslipidemia in-vitro diagnostic (IVD) test that aids in the management of lipoprotein disorders associated with cardiovascular disease risk. The method consists in the quantification of an advanced lipoprotein profile extracted from a patient's serum/plasma and measured by nuclear magnetic resonance (NMR) spectrometer. The resulting NMR spectra is the input of the Liposcale® algorithm based on 2D NMR spectra which provides detailed information on the serum/plasma lipoprotein profile including 23 clinical variables.
101187	ColoScape Colorectal Cancer Detection Test	Oncology (Colorectal Cancer, Solid organ neoplasia), multiplex real-time PCR based Xenonucleic acid (XNA) mediated PCR clamping technology, cfDNA, Plasma or formalin-fixed paraffin-embedded tissue, report of colorectal cancer-associated mutations in genes including APC (codons 1309, 1367, 1450 and 876), BRAF (codon 600), CTNNB1 (codons 41 and 45), KRAS (codons 12 and 13), NRAS (codons 12 and 13), PIK3CA (codon 545), SMAD4 (codon 361) and TP53 (codons 175, 248 and 273). And the methylation genes (MYO1G, KCNQ5, C9ORF50, FLI1, CLIP4, ZNF132 and TWIST1).
101188	Genesys Carrier Panel	Inherited disorders, NGS of 143 Genes utilizing buccal swab
101190	RFC1 Repeat Expansion	Neurological disorders (Ataxia), DNA analysis, Next generation sequencing analysis of variant in the RFC1 gene, specimens, blood, saliva, or buccal, reported as repeat expansion in the RFC1 gene detected or not detected
101193	Solid Tumor Expanded Panel	Targeted genomic sequence analysis panel, solid organ neoplasm, DNA and RNA by next-generation sequencing, 523 genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden
101194	PersonalisedRX	Drug Metabolism or processing (Multiple Conditions) buccal specimen. Human DNA analysis, 20 gene variant analysis with CYP2D6 deletion/duplication. variants are analyzed and genotype/phenotype reported
101196	Qlear Urine Pathogen Panel	Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogens, identification of DNA from 16 bacterial organisms and 1 fungal organism, multiplex amplified probe technique via real-time [RT]-PCR. Performed on urine specimens. Results reported are diagnostic and semi-quantitative for the following organisms: Acinetobacter baumannii - Citrobacter freundii - Enterobacter aerogenes - Enterobacter cloacae - Enterococcus faecalis - Enterococcus faecium - Escherichia coli - Klebsiella oxytoca - Klebsiella pneumoniae - Morganella morganii - Proteus mirabilis - Proteus vulgaris - Providencia stuartii - Pseudomonas aeruginosa - Staphylococcus saprophyticus - Streptococcus agalactiae - Candida albicans Positive results are reflexed to Antibiotic Resistance Gene (ABR) panels

101197	Phenylalanine and Tyrosine, Self-Collect, Blood Spot	Hyperphenylalaninemia monitoring by patient collected blood card sample, measurement of phenylalanine and tyrosine, liquid chromatography-tandem mass spectrometry
101198	Tyrosinemia Follow-Up Panel, Self-Collect, Blood Spot	Tyrosinemia type I monitoring by patient collected blood card sample, quantitative measurement of tyrosine, phenylalanine, methionine, succinylacetone, nitisinone, liquid chromatography-tandem mass spectrometry
101199	Qlear Urine Pathogen Panel ABR Reflex	Antibiotic resistance gene detection by nucleic acid (DNA or RNA), genitourinary pathogens, by multiplex amplified probe technique via real-time [RT]-PCR. Performed on positive urine specimens containing one or more of 17 target pathogens. Results are reported using the Arkstone Antimicrobial Stewardship format for 23 ABR genes: - APH(3')-VI - AAC(6')-Ib - AAC(6')-Ib-cr - blaMOX/blaCMY - blaCTX-M (subset 1) - dfrA - gyrA - mcr-1/mcr-2 - sul1/sul2 - MecA/MecC - Mef(A)/Ere(B) - VanA/VanB - blaKPC - blaIMP - blaNDM - blaVIM - blaOXA - blaFOX - blaTEM - erm(B) - cfr - blaPER - blaCTX-M (subset 2)
101200	Respiratory pathogen with ABR (RPX)	Infectious Disease, Respiratory tract infection, 17 bacteria, 8 fungus, 13 virus and 16 antibiotic resistance markers. upper and/or lower respiratory specimen, each microbial agent reported ad detected or not detected. antibiotic resistance marker reported as detected or not detected
101201	Medication Management - Neuropsychiatric Panel	Neuropsychiatric (e.g., depression, anxiety, attention deficit hyperactivity disorder [ADHD]), genomic analysis panel, buccal specimen, variant analysis of 15 genes (58 variants), including reported phenotypes, impacted gene-drug interactions, and deletion/duplication analysis of CYP2D6 via real-time [RT]-PCR
101202	UTI with ABR Detection Assay, Bridge Diagnostics – **Revise 0321U**	▲**0321U** Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogens, identification of 20 or more bacterial and fungal organisms, reported as detected or not detected and, for pathogens detected, associated antimicrobial susceptibility testing for ~~identification of~~ 16 ~~associated~~ or more pathogens and 2 or more antibiotic-resistance genes, multiplex amplified probe technique
101203	Leison infection (Wound)	Infectious disease, wound, ulcer, post-surgical wound, DNA/RNA analysis. 34 microbial agent causing lesion infection, including causative agent for dermatitis and ulcer. 21 antibiotic resistance marker. DNA/RNA analyzed and reported as detected or not detected
101204	NaviDKD™ Predictive Diagnostic Screening for Kidney Health	Diabetic Kidney Disease. Chemical(s) analyzed - protein (Advanced Glycation End Products), blood (plasma) sample is analyzed for the levels of specific AGEs (Carboxymethyllysine, methylglyoxal hydroimidazolone and carboxyethyl lysine) using HPLC-MS (High Performance Liquid Chromatography) triple quadrupole mass spectrometry. Those measurements, along with current HbA1c and eGFR test results are used in a predictive algorithm to calculate a predictive risk score
101205	PromarkerD	Nephrology (chronic kidney disease), multiplex enzyme-linked immunosorbent assay (ELISA) of Apolipoprotein A4 (ApoA4), CD5 antigen-like (CD5L), and Insulin-like Growth Factor Binding Protein 3 (IGFBP3) combined with clinical data, including HDL and eGFR from plasma (isolated fresh or frozen), algorithm reported as probability score and risk category for developing diabetic kidney disease and/or future kidney function decline

101206	Oncomine Dx Target Test - IDH1	Targeted genomic sequence analysis panel, cholangiocarcinoma, DNA analysis, 1 gene, interrogation for sequence variants and rearrangements, reported as presence/absence of variants and associated therapy(ies) to consider
101207	IriSight™ Prenatal Analysis – Proband **Revise 0335U**	▲0335U Rare diseases (constitutional/heritable disorders), whole ~~gen~~ex~~ome~~ome sequence analysis, including small sequence changes, copy number variants, deletions, duplications, mobile element insertions, uniparental disomy (UPD), inversions, aneuploidy, mitochondrial genome sequence analysis with heteroplasmy and large deletions, short tandem repeat gene expansions, fetal sample, identification and categorization of genetic variants
101208	IriSight™ Prenatal Analysis – Comparator **Revise 0336U**	▲0336U Rare diseases (constitutional/heritable disorders), whole ~~gen~~ex~~ome~~ome sequence analysis, including small sequence changes, copy number variants, deletions, duplications, mobile element insertions, uniparental disomy (UPD), inversions, aneuploidy, mitochondrial genome sequence analysis with heteroplasmy and large deletions, short tandem repeat gene expansions, blood or saliva, identification and categorization of genetic variants, each comparator genome (eg, parent)
101209	GI assay (Gastro Intestinal pathogen with ABR)	Infectious agent detection by nucleic acid DNA/RNA gastro intestinal pathogens, identification of 31 bacterial, viral and parasitic organisms and identification of 21 associated antibiotic resistance genes, multiplex amplified probes technique.
101210	Genesys PGx Profile	Genotyping DNA, via multiplex PCR and mass spectrometry of 18 genes, utilizing Buccal swabs, drug-metabolism report comparison of 18 genes
101211	UTI ID Detection Assay, Bridge Diagnostics	Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogens, identification of 20 or more bacterial and fungal organisms, reported as detected or not detected, multiplex amplified probe technique
101212	Envisage Barrett's Esophagus Risk Classifier Assay	Gastroenterology (Barrett's esophagus), P16, RUNX3, HPP1, and FBN1 DNA methylation analysis using PCR, formalin-fixed paraffin-embedded tissue, with prognostic and predictive algorithm reported as risk score for progression to high-grade dysplasia or esophageal cancer
101213	Oncomine Dx Target Test **Revise 0022U**	▲0022U Targeted genomic sequence analysis panel, ~~cholangiocarcinoma and~~ non-small cell lung neoplasia, DNA and RNA analysis, ~~1~~ 23 genes, interrogation for sequence variants and rearrangements, reported as presence/absence of variants and associated therapy(ies) to consider
101214	Branched-Chain Amino Acids, Self-Collect, Blood Spot	Maple-syrup urine disease monitoring by patient collected blood card sample, quantitative measurement of allo-isoleucine, leucine, isoleucine and valine, liquid chromatography-tandem mass spectrometry